

**REMARKS**

Reconsideration of this application is respectfully requested. Claim 20 has been amended to recite a method of treating premenstrual syndrome in a patient in need thereof who failed to respond to initial treatment with a selective serotonin reuptake inhibitor other than escitalopram. Support for this amendment is found in the specification at, for example, page 5, lines 16-19, and in original claims 5 and 8. Claim 20 has also been amended to remove the phrase “as the sole active ingredient.” New claim 38 has been added. Support for new claim 38 is found in the specification at, for example, page 10, lines 7-9. Claims 20-38 are pending and at issue.

**Obviousness-Type Double Patenting Rejection**

Claims 20-37 have been provisionally rejected for obviousness-type double patenting over claims 1-8 in co-pending U.S. Patent Application No. 10/984,536 (“the ‘536 Application”). Applicants respectfully submit that a terminal disclaimer is not required to be filed in this application pursuant to M.P.E.P. §804 since the present application was filed before the ‘536 Application (i.e., the ‘536 Application was filed on November 8, 2004 and claims priority to a November 7, 2003 provisional application), and the subject matter claimed in the ‘536 Application has not yet been found to be allowable.

M.P.E.P. §804(I)(B)(1) provides:

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of ... two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. ... If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer.

Because the present application is the earlier-filed application and allowable but for this provisional rejection, the provisional rejection should be withdrawn.

**Rejection Under 35 U.S.C. §103(a)**

Claims 20-37 have been rejected under 35 U.S.C. §103(a) as obvious over Boegesoe et al. (U.S. Patent No. 4,943,590) in view of Norden (U.S. Patent No. 5,789,449) and the Merck Manual (16<sup>th</sup> ed., 1992, p. 1791). The Examiner cites Boegesoe as disclosing a method of treating depression, but not premenstrual syndrome (PMS), using escitalopram; cites Norden as disclosing a method of treating PMS using a serotonin reuptake inhibitor, such as citalopram; and cites the Merck Manual as disclosing that depression is a symptom of PMS. According to the Examiner, it would have been obvious for one of ordinary skill in the art to administer escitalopram to patients suffering from PMS because both premenstrual syndrome and depression are treatable by inhibition of serotonin reuptake.

Applicants respectfully traverse this rejection and request reconsideration.

Claim 20 has been amended to recite a method of treating premenstrual syndrome in a patient in need thereof who failed to respond to initial treatment with a selective serotonin reuptake inhibitor other than escitalopram. None of the cited references disclose or suggest that escitalopram (as opposed to any other treatment) could effectively treat PMS, let alone in the presently claimed patient population.

As acknowledged by the Examiner, Boegesoe does not “disclose ... a method of treating premenstrual syndrome with escitalopram” (February 7, 2006 Office Action, page 4, first paragraph).

Norden discloses a method of treating PMS (referred to as late luteal phase dysphoric disorder (LLPDD)) by administering a serotonin re-uptake blocker, with fluoxetine and norfluoxetine being preferred. (Norden, col. 2, lines 55-57; col. 6, lines 31-42 and 50-51; and col. 9, line 65 to col. 10, line 26). Norden does not disclose or suggest that escitalopram would be effective in the treatment of PMS in patients who failed to respond to initial treatment with a selective serotonin reuptake inhibitor other than escitalopram.

Furthermore, to establish obviousness, there must be a reasonable expectation of success when combining or modifying the references. Here, Boegesoe, Norden, and the Merck Manual would not have provided one of ordinary skill in the art with a reasonable expectation of success in using escitalopram to treat PMS in patients who failed to respond to initial treatment with a different selective serotonin reuptake inhibitor, such as fluoxetine. Rather, one of ordinary skill would have been discouraged from using escitalopram to treat these patients because, by definition, they would have already failed to respond to a selective serotonin reuptake inhibitor. Thus, one of ordinary skill would have had no motivation to use another selective serotonin reuptake inhibitor after a similar treatment had previously proven unsuccessful.

For the foregoing reasons, Boegesoe, Norden, and the Merck Manual fail to render obvious claims 20-38. Therefore, applicants respectfully request withdrawal of this rejection.

### Conclusion

In view of the above amendment and remarks, applicants believe the pending application is in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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